K123756

Covalon Technologies Inc.
A Unique Medical Technologies Company

ISO 13485:2003 CERTIFIED

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Special 510(k) Summary of Safety and Effectiveness

1. Sponsor information

Covalon Technologies Inc.
405 Britannia Road East, Suite #106
Mississauga, Ontario,
Canada L4Z 3E6

AUG 16 2013

Contact person:	Kim Crooks Vice President of Operations
Phone number:	1-905-568-8400 Ext 265
Fax number	1-905-568-5200
Date of Summary	06 Aug 2013

2. Device name and classification

Proprietary name:	ColActive® Transfer
Common Name:	Collagen Wound Dressing
Device Classification:	Unclassified
Classification Panel:	General and Plastic Surgery
Product Code:	KGN

3. Predicate devices

Manufacturer	Device	510(k) number
Covalon Technologies	ColActive® Collagen Wound Dressing	K050177
Molnlycke Health Care US, LLC	Mepilex ® Transfer Ag	K123892

4. Indications for use

ColActive® Transfer is indicated for management of full and partial thickness wounds including: pressure ulcers, diabetic ulcers, ulcers caused by mixed vascular etiologies, venous ulcers, second degree burns, donor and graft sites, abrasions, dehisced surgical wounds, traumatic wounds healing by secondary intention.

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5. Device Description

ColActive® Transfer is a modification to the existing ColActive® Collagen Wound Dressing previously cleared under K050177 on 27th April 2005. ColActive® Transfer is composed of the same base matrix material; collagen and sodium alginate and is made from substantially an equivalent manufacturing process as the predicate. The new product, ColActive® Transfer is a pliable, absorbent, perforated, and biocompatible dressing. ColActive® Transfer dressings absorb and transfer moisture such as wound fluid and maintains a moist environment at the wound surface. The dressings can be cut to fit specific wounds and can be layered for the management of deep wounds. ColActive® Transfer dressings contain multiple holes that are evenly distributed across the surface area in order to facilitate the movement of excess exudates through the dressing and away from the wound. The new product will be supplied sterile packaged in a single use heat sealed medical grade foil pouch. The single use primaries will be packed, with a product insert, into cartons for distribution.

6. Technological Characteristics:

ColActive® Transfer is a pliable and absorbent dressing that controls wound moisture levels through fluid absorption and transfer.

The predicate and the proposed devices have the same intended use and basic fundamental scientific technology. The only modifications to the predicate device consist of increased amounts of absorbing components (collagen and alginate) as well as flattening and perforating after lyophilization. These modifications confer additional absorption capacity, while facilitating passage of excess fluid to secondary dressings, if required. The modifications do not affect the safety but improve the effectiveness of the device.

ColActive® Transfer will be manufactured according to the product specifications and under good manufacturing practices to ensure the device is safe and effective for its intended use.

7. Performance Data

ColActive® Transfer performance testing, includes bench testing such as heat stability, crosslinking, fluid/water absorption, as well as visual testing (Defect Free surface and even dressing thickness) which confirmed that ColActive® Transfer is substantially equivalent to the predicate devices with regard to materials, intended use and technological characteristics, pursuant to section 510(k).

8. Substantial equivalence

ColActive® Transfer has the following similarities to ColActive® Collagen Wound Dressing which previously received 510(k) concurrence under K050177 on 27th April 2005:

- has the same indicated use,

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- use the same operating principle,
- incorporate the same basic dressing design,
- incorporate the same materials, and
- are packaged and sterilized using the same materials and processes.

In summary, the modified device, ColActive® Transfer has the same fundamental scientific technology and the same intended use as the predicate device ColActive®. The changes that were made improve the fluid handling capability of the dressing and do not affect the safety of the device. Therefore, the modified device ColActive® Transfer is substantially equivalent to its predicate ColActive®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Kim Cooks
Vice President of Operations
Covalon Technologies Incorporated
405 Britannia Road East, Suite 106
Mississauga, Ontario Canada L4Z 3E6

Re: K123756
Trade/Device Name: ColActive® Transfer
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 18, 2013
Received: July 25, 2013

Dear Ms. Cooks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K123756

Device Name: **ColActive® Transfer**

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ColActive® Transfer, is indicated for management of full and partial thickness wounds including pressure ulcers, diabetic ulcers, ulcers caused by mixed vascular etiologies, venous ulcers, second degree burns, donor and graft sites, abrasions, dehisced surgical wounds, traumatic wounds healing by secondary intention.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K123756